DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Detroit District Office
Central Region
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Detroit, MI 48207
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CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
2003-DT- 07

December 10, 2002

Richard C. Herzberger
President
Serv-A-Pure Company
1101 Columbus Avenue
Bay City, MI 48708

Dear Mr. Herzberger:

Investigator Paige E. Wilson conducted an inspection of your medical device manufacturing firm dated September 17-18, 2002. At the conclusion of that inspection, Investigator Wilson issued to you a FORM FDA-483, list of Inspectional Observations. The inspection found that your firm is operating in serious violation of the Federal Food, Drug, and Cosmetic Act, (the Act).

Our inspection found that your firm is operating in violation of the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, in that the methods used in, or the facilities used for, the design, manufacturing, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use, are not in compliance with that regulation. Specifically, the Water Purification Systems manufactured for use in hemodialysis treatment centers, are adulterated within the meaning of Section 501(h) of the Act as follows:

1. You failed to appoint a manager with executive responsibility to be the "Management Representative" (FDA-483 # 1) as required by 21 CFR 820.20(b)(3).

2. You failed to establish a written procedure to address the management review requirements (FDA-483 # 2) of the management responsibility section of 21 CFR 820.20(c).

3. You failed to establish a procedure for quality audits, and you failed to conduct any quality audits (FDA-483 # 3) as required by 21 CFR 820.22.

4. You failed to document performance of all the required design control elements, as required by 21 CFR 820.30(c) and (d). Specifically, the design input and design output documents have not been signed and dated as noted in (FDA-483 #4).

5. You failed to document receiving acceptance activities for incoming components and supplies (FDA-483 # 5, 6.c. and # 8) as required by 21 CFR 820.80(b).

6. You failed to establish finished product acceptance procedures and acceptance criteria, (FDA-483 # 6.b.) for the water purification systems, as required by 21 CFR 820.80(d).

7. You failed to establish procedures for and documentation of the calibration of inspection, measuring, and test equipment such as the [redacted] Equipment, (FDA-483 # 6.d. and 9) as required by 21 CFR 820.72.

8. You failed to establish a procedure for controlling production and process changes (FDA-483 # 6.a.) as required by 21 CFR 820.70(b).

9. You failed to establish a written procedure to address all the requirements for corrective and preventive action (FDA-483 # 10) as required by 21 CFR 820.100.

The above is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure adherence to each requirement of the Quality System Regulation. Other Federal agencies are advised of the issuance of all Warning Letters about medical devices so they may take this information into account when considering the award of contracts. Additionally, pending 510(k) or PMA applications and export approval requests may not be approved until the above violations are corrected.

We request that you take prompt action to correct these violations and to ensure that your device manufacturing operations are in full compliance with the Act and regulations promulgated thereunder. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice, such as seizure and/or injunction.

We acknowledge receipt of your October 10, 2002 letter directed to Investigator Paige Wilson, written in response to the FDA-483. The actions described in your letter indicate that you have attempted to correct the specific observations listed on the FDA-483, however we are concerned that some of the corrections have been designed and implemented without performing a thorough evaluation of all your production and records systems, and they may not address all the requirements of the Act and the regulations.

We would like to suggest you acquire a copy of the publication, Medical Device Quality Systems Manual: A Small Entity Compliance Guide HHS Publication FDA 97-4179. The manual can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, telephone (202) 512-1800. It is also available on the World Wide Web at www.fda.gov/cdrh/dsma/gmp_man.html. It is designed to assist the small medical device firm in setting up a Quality Management System in compliance with the regulations.

Specifically concerning your response letter:

1. Management Representative. You amended your Quality Manual, section 2.1 to state either the President or the Vice President shall be the management representative. The duties of those officers in sections 2.2 and 2.3 lack additional details covering this new assignment. We believe your response to this point does not adequately address the violation. You should carefully review all the requirements of Subpart B – Quality System Requirements, 21 CFR 820.20, Management Responsibility. This regulation defines the Management Representative duties, and explains the broad range of responsibilities the position entails.

2. Management Reviews. Your amended Quality Manual, section 2.7 lacks sufficient detail, and includes Quality Audits that should properly be addressed separately, as they are subject to 21 CFR 820.22, a separate regulation..

3. Quality Audits. You refer to Section 2.7 of your Quality Manual, however the subject is covered in slightly more detail in section 6.2. We believe you need a more detailed audit procedure, and suggest you review Chapter 17 of the FDA manual recommended above.

4. Design Control and Design Inputs and Outputs. Your response to FDA-483 observation # 4 addresses the specific observation that the records were not signed and dated. We are concerned that the records referred to in this observation are maintained on a computer system, and your response states in Section 3.3, "All critical design records and documents are dated and signed by an engineer on staff." You need to establish and maintain a system of hard copy design records, such as required by the Design History File element of the Design Control regulation. These signed and dated documents must be considered the official design records.
Continuing our review of your response to #4, you referenced the expanded sections 3.3 through 3.6 of your quality manual, therefore we have also reviewed that material. Section 3.6, Quality Engineering Design Practices, appears to be your attempt to address the Design Control elements required by 21 CFR 820.30, but you have not included all the elements listed in that regulation, and you have modified the order in which they are listed. We believe you should review the Design Control regulation, and we also suggest you review Chapter 3 of the FDA publication manual recommended above.

5. Production and Process Control. FDA-483 observations 5 – 9 were all included under this caption although in fact they represent violations of several different subparts of the regulation. SECTION 5 of your revised quality manual is your response to all of these observations. There is a lack of details for some of these procedures, and we suggest you re-examine them for organization and content. For instance your revised components acceptance procedure, Section 5.3, lacks details as to how you can determine, "If everything checks out to be good, ..."

6. Corrective and Preventive Action Control. Section 6 of your revised Quality Manual represents your response to FDA-483 observation 10. The parts of section 6 describe handling of complaints, returned product, failing components, and quality audits, however this section does not address the concept of investigating data from those and other sources of information to determine if problems exist, and taking corrective action that may involve product or process revisions and/or recalls or field corrective actions. Furthermore, as stated under #2 above, the procedure for performing quality audits does not belong in this section.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of any steps you have taken, or intend to take, to bring your firm into compliance. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the corrections will be implemented.

Your response should be directed to Melvin O. Robinson, Compliance Officer, at the above address.

Sincerely yours,

Joann M. Givens
Director, Detroit District